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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/884,481      | 06/20/2001  | Takao Hamakubo       | P21128              | 9557             |

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EXAMINER

FOLEY, SHANON A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1648

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/884,481

**Applicant(s)**

HAMAKUBO ET AL.

**Examiner**

Shanon Foley

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.  
4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-8 and 15-28 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/2/4.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

In the amendment submitted April 2, 2004, applicant amended the specification on page 6 and page 8. Although applicant does not point to specific support in the original disclosure in the "remarks" section, it is noted that support can be found throughout the specification, see the second full paragraph on page 2 to line 2 of page 4 and the first full paragraph on page 5 and the second full paragraph on page 6 for example.

### ***Election/Restrictions***

Applicant amended claims 1, 2 and added new claims 15-28. Claims 1-28 are pending in the application. This application contains claims 9-14 drawn to an invention nonelected with traverse in the reply filed on November 4, 2002. Applicant submits that the restriction requirement should be withdrawn because it would not be a serious burden to examine all of the groups because they are related to one another. Applicant requests a rejoinder of the non-elected claims upon allowance of the allowed claims.

Applicant's arguments have been fully considered, but are found unpersuasive. The restriction requirement meets all of the criteria of a proper restriction, including the existence of a serious search burden. The serious burden of searching for each of the distinct inventions is established by an explanation and reasons for how each invention is independent and distinct. A serious search burden is also established by the fact that each invention is categorized into separate classifications in the art, indicating divergent subject matter. These facts are summarized in the second full paragraph on page 4 of the requirement.

Applicant's request for a rejoinder upon indication of allowable subject matter has been considered. The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

**"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined."** (emphasis added)

Therefore, in accordance with M.P.E.P. § 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. However, in the instant case, applicant is not entitled to a rejoinder of the claims withdrawn from consideration because applicant elected a method and not a product.

Accordingly, a complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 1-8 and 15-28 are under consideration.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 21 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 21 and 25 have been amended to specify that the budded baculovirus expresses an intracellular organelle membrane bound protein or a non-receptor protein,

which are selected from a list of proteins. However, some of the proteins listed are not commensurate in scope with the required intracellular organelle membrane bound proteins or a non-receptor proteins. The discrepancy between the required type of protein and the proteins listed are proteins involved in adhesion and proteins involved in antigen presentation. These proteins are not intracellular organelle membrane bound proteins or non-receptor proteins. Therefore, it is unclear which types of proteins applicant intends to claim. This rejection also affects claims 3-8.

Previous rejections made under this paragraph are withdrawn in view of applicant's arguments on page 13 of the response.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 15-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grabherr et al. (Biotechniques. 1997; 22 (4): 730-735, cited previously), Possee (Current Opinion in Biotechnology. 1997; 8: 569-572, cited previously) and in further view of Nohturefft et al. (PNAS. 1999; 96: 11235-11240) and Duncan et al. (Journal of Biological Chemistry. 1997; 272 (19): 12778-12785).

Applicant argues that the proteins disclosed in Boublik and Grabherr are cell membrane-associated proteins and would be expressed on the surface of a baculovirus. Applicant asserts that expressing and recovering intracellular organelle membrane-bound proteins on the surface of budded baculoviruses is unexpected.

Applicant's arguments have been fully considered, but are found unpersuasive in view of the teachings of the prior art cited below.

The claims have been amended to require a method for preparing and recovering a budded baculovirus expressing an intracellular organelle membrane-bound protein or a non-receptor protein in an insect cell. The protein is an Endoplasmic Reticulum-associated protein, a Golgi Apparatus-associated protein and more specifically SREBP2.

Duncan et al. teach SREPB-2 control the metabolism of cholesterol and are bound to the membrane of the ER, see the abstract and introduction sections. Duncan et al. also teach making an SREPB-2/Ras fusion protein to identify a cleavage site within the protein, see "Construction of pTK-HSV-BP2-Ras-T7" in the Experimental Procedures. Duncan et al. do not specifically teach that SREPBs are transported to the Golgi Apparatus.

However, Nohturefft et al. also teach SREPBs are present in the membrane of the ER and are involved in the synthesis of cholesterol and its uptake from plasma lipoproteins. Nohturefft et al. teach that in sterol-depleted cells, SCAP escorts SRBP2 to the Golgi Apparatus. See the abstract, introduction and the last paragraph of the discussion section.

Neither Duncan et al. nor Nohturefft et al. teach expressing SREPB-2 on the surface of a baculovirus.

However, one of ordinary skill in the art at the time the invention was made would have been motivated to express SREPB-2 in a baculovirus system to study the protein, see the first full paragraph of the second column on page 570 of Possee or to

screen for ligands that may directly interact with SREPB-2, see the first paragraph of the introduction section of Grabherr et al.

Contrary to applicant's assertions, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for expressing and recovering a non-receptor protein or an intracellular organelle membrane-bound protein, such as SREPB-2, on the surface of budded baculoviruses. Grabherr et al. teach the specific mechanisms for expressing a protein on the surface of a baculovirus by fusing the protein of interest to the entire baculovirus major coat protein gp64, see Ac-mars41 and Ac-promars41 in Figure 1 and the first full paragraph of the first column on page 734. Possee reviews the teachings of Grabherr et al. in the paragraph bridging the columns on page 570 and concludes that any eukaryotic protein can be expressed and displayed on the baculovirus surface, see the conclusion on page 571. Therefore, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for expressing and recovering the SREPB-2 protein of Duncan et al. and Nohturefft et al. on the surface of the baculovirus of Grabherr et al. because Duncan teach studying SREPB-2 by forming a fusion protein and Grabherr et al. teach that expressing proteins on the surface of a baculovirus requires fusing a protein of interest to the baculovirus major coat protein, gp64. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute the Ras portion of the fusion protein of Duncan et al. for the baculovirus gp64 protein of Grabherr et al. to express SREPB-2 on the surface of a baculovirus, since, according to Possee, any eukaryotic protein can be expressed and displayed on the surface of a baculovirus in light of the teachings of Grabherr et al. Applicant has not provided any

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evidence of unexpected results. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

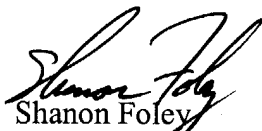
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Shanon Foley  
Patent Examiner, 1648